In the context of demographic change, Europe is facing an acute healthcare challenge. In no area is this more apparent than in Alzheimer’s disease (AD) and dementia. AD and related dementias affect nearly 50 million individuals worldwide with prevalence projected to double over the next twenty years.

So far there is no cure for AD and challenges in the evaluation of early disease interventions within the current assessment systems have not changed. Consequently, the precision medicine approach to health funding requires new models that encompass all the available evidence for the identification of best suited treatments for different groups within the AD continuum.
WHAT IS ROADMAP?

The Real world Outcomes across the Alzheimer’s Disease (AD) spectrum for better care: Multi-modal data Access Platform (ROADMAP) project is a public private consortium with 25 partners from Europe, coordinated by the University of Oxford and Novartis.

ROADMAP brings together leading institutions and companies with an interest in improving the situation of people with AD. Therefore, ROADMAP’s goal is to establish a sustainable platform for real world evidence (RWE) data to better inform consensus and decisions. The project will deliver guiding principles and recommendations on incorporating RWE in healthcare systems.

ROADMAP’s OBJECTIVES

• Define and catalogue scales and consensus-based methodologies for identifying AD outcomes from routinely collected data.

• Identify and pool AD-related RWE data and establish solution options for how to combine different RWE sources with RCT data supporting pharmacoeconomic evaluation.

• Develop and validate a core disease progression model combining diverse datasets to facilitate analysis of disease trajectories and effect of interventions on disease trajectories.

• Develop a proof of concept AD cost-effectiveness and budget impact model for HTA agencies, regulators, service providers, industry, payers and carers.

• Develop guiding principles and recommendations from HTA/payers/regulators for the development and incorporation of RWE into clinical and market access development plans for AD.

• Develop and implement a communication strategy focusing on the needs of patients and professionals.

• Develop an Ethical, Legal, and Social Implications (ELSI) framework with extensive patient involvement for the development and application of RWE in AD.

• Develop a full plan for phase 2 of the ROADMAP initiative that addresses identified gaps and pitfalls, and exploits promising solutions to their full potential for development of a European RWE platform in AD.

In order to achieve this ROADMAP will use and analyse data of subjects from:

| 75 national databases and clinical registries | n ≈ 80M |
| More than 40 cohorts | n ≈ 2M |
| Several studies using wearables and smart devices | n ≈ 100K |
| 5 dementia relevant trials | n ≈ 100K |

ROADMAP welcomes additional database providers, interested universities, institutions as well as companies to further expand its Europe-wide network towards a potential onboarding for a Phase 2

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